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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yajun Guo

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EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

NOTIFICATION DATE

DELIVERY MODE

04/02/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No. 09/915,746	Applicant(s) GUO ET AL.	
	Examiner Karen A. Canella	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-17, 19 and 20 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 15 and 19 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claims 19 and 20 have been amended. Claim 14 has been canceled. Claims 15-17, 19 and 20 are pending and under consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Grinnell (U.S. 5,270,168) as evidenced by Trefzer et al (BMC Cancer, 11 January 2006, vol. 6, pp. 12, cited in a previous action).

Claim 15 is drawn to a method comprising the steps of combining a sample from a human with a monoclonal antibody which specifically binds to an antigen, wherein said antigen is specifically bound by the antibody produced by the hybridoma deposited under ATCC Accession No. HB-12588, wherein said antigen is present on the membrane and in the cytoplasm of human melanoma cells, said antigen not being present in normal melanocytic cells detectable by the antibody secreted by the hybridoma HB-12588, wherein said monoclonal antibody competitively inhibits specific binding of the antibody secreted by HB-12588 to the antigen and detecting formation of immune complexes, wherein the sample is bodily fluid.

Claim 19 is drawn to a method comprising the steps of combining a sample from a human with a monoclonal antibody which specifically binds to an antigen, wherein said antigen is specifically bound by the antibody produced by the hybridoma deposited under ATCC Accession No. HB-12588, wherein said antigen is present on the membrane and in the cytoplasm of human melanoma cells, said antigen not being present in normal melanocytic cells detectable by the antibody secreted by the hybridoma HB-12588, wherein said monoclonal antibody competitively inhibits specific binding of the antibody secreted by HB-12588 to the antigen, wherein the antibodies are monoclonal antibodies which are conjugated to a technetium 99, a fluorescer, a radio-opaque dye or an enzyme, and wherein said sample is a bodily fluid.

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It is noted that the recitation of a “method for detecting the presence of melanoma in a human” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is further noted that the phrase “as indicative of the presence of melanoma cells” is not given patentable weight when comparing the claims to the prior art as it simply expresses the intended result of a process step positively recited, see MPEP 2111.04.

The specification teaches that the SM5-1 antibody was deposited with the Accession No. HB-12588. Trefzer et al provides evidence that the SM5-1 antibody binds to the ED-A isoform of fibronectin.

Grinnell discloses a method wherein “wound fluid type B” is contacted with an anti-ED-A antibody in a Western Blot procedure (column 19, lines 32-34 and column 24, lines 53-56). Grinnell discloses that the antibody may be radiolabeled, fluorescently labeled or coupled to another moiety conducive to visualization (column 5, lines 66-68). Wound fluid type B fulfills the required limitation of a “bodily fluid”.

The reference does not specifically teach that the anti-ED-A antibody competitively inhibits the anti-SM5-1 antibody of the instant invention. However, the instant method appears to use the same antibody in terms of binding specificities to the ED-A fibronectin, absent a showing of unobvious differences. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 16 and 17 are objected to as being dependent upon a rejected base claim, but

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would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 20 is free of the art.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen A Canella/

Primary Examiner, Art Unit 1643